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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,960	03/12/2001	John A. Howard	10015	8289

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GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
925 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

18

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,960

Applicant(s)

HOWARD ET AL.

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed on 06/13/2003 in reply to the Office action of 1/15/03 has been entered. Claims 17 and 26 have been cancelled. Therefore, claims 1-16 and 18-25 are pending and are under consideration. The Declaration under 37 C.F.R. 1.132 of Dr. Elizabeth Hood filed on 06/13/03 has been considered.

All previous rejections and objections not set forth below have been withdrawn.

Claim Objections

In claim 8 "_wherein" should be changed to ---, and wherein---, for clarification.

In claim 21, "wherein" should be changed to ---, and wherein---, for clarification.

Claim Rejections - 35 USC § 112

1. Claims 11, 15-16 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 1/15/03. Applicant's amendment to the claims in the response filed 6/13/03 does not obviate the rejection.

Claims 11 and 24 are indefinite because the claims do not recite the specific wash and hybridization conditions required for "highly stringent" conditions. Applicant asserts that "highly stringent" conditions are discussed at pages 6-8 of the specification (response, page 6). However, the specification only describes an exemplary high stringency conditions, and does not clearly set forth the specific wash and hybridizations

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conditions required for Applicant's "highly stringency " conditions. The phrase is open to individual interpretations, and hence the metes and bounds of the claims are unclear.

Claims 15 and 25 remain rejected because what is considered "commercial quantities" is unknown. On page 6 of the response, Applicant states that production levels of 0.01% of laccase are useful, with 0.1% are preferred. However, it is unclear whether these levels of laccase are considered to be "commercial levels". It is suggested that the phrase be deleted.

Claim 16 is indefinite because it depends upon claim 18. A claim can only depend upon a previous claim.

Claim 25 is indefinite because the steps of producing a biomass are missing. Also, the claim lacks correlation between the preamble and the last method step.

Claim Rejections - 35 USC § 112

Claims 1-16 and 18-25 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling for claims limited to a method for producing laccase in plants at levels of about 0.1%, 1%, 10% of the total soluble protein of the plant by expressing a construct comprising an isolated nucleotide sequence encoding laccase under the control of a seed-specific promoter and signal sequence, wherein the laccase is targeted to the cell wall of the seed, and transgenic plants, plant cell, and seed comprising said construct. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 1/15/03. Applicant's

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arguments and the Declaration of Dr. Hood filed on 06/13/03 have been considered but not all are persuasive.

Applicant argues that the invention as claimed is enabled by the instant specification because laccase has been successfully produced at higher levels in a transgenic plant by directing expression of laccase to the seed, and to the cell wall of the plant. Applicant also argues that before Applicant's invention, laccase was expressed in plants but at very low levels or plants have died as result of expressing the laccase in non-seed and non-cell wall tissues of the plant (response, page 7, 3rd full paragraph). Applicant further argues that the source of the laccase-encoding sequence, or seed preferred promoter or signal sequence employed in the invention is not important as various laccase-encoding sequences, seed-specific promoters and signal sequences are known and widely used by a skilled artisan (response, page 8, 1st full paragraph). Finally, Applicant attempts to demonstrate via citations to various patents and non-patent references that various laccase-encoding nucleotide sequences are available in the prior art.

These arguments are not persuasive for the following reasons: 1) the rejected claims do not recite a seed-specific promoter and signal sequence that allow expression of laccase to be targeted to the seed, preferentially to the cell wall of the plant, so that production levels of 0.01%, 0.1%, 1% and 10% of the enzyme can be achieved. 2) The lack of recombinant production and commercially adequate yields of the prior art laccase was due to the fact that neither the enzyme nor the gene encoding such enzyme has previously been isolated and/or purified and sequenced, and until now only

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fungus and plant laccase encoding genes have been isolated. 3) Production of foreign enzymes that are functional in plant based expression systems are unpredictable as evidenced by Becker et al disclosed in the Office action of 1/15/03. 4) The citations to show availability of various laccase-encoding genes known in the prior art are not given weight because the references were not provided. However, to the extent that they can be evaluated, it appears that only plant and fungus laccase have been characterized, and therefore, claims that employ any laccase encoding nucleotide sequence are not enabled. In addition, Applicant's argument that prior attempts to express higher levels of laccase in plants were not successful is not persuasive because no single reference to support the conclusion has been provided. In addition, Applicant has neither addressed the rejection to claims that recite % of sequence identity and hybridizing sequences, nor Applicant has provided evidence showing that the plant and fungus laccase nucleotide sequences share said structural identity.

The Declaration under 37 CFR 1.132 of Dr. Elizabeth Hood has been considered. The Declaration states that expression levels of at least 10% of laccase (TSP) in transgenic maize plants and progeny have been achieved with the methods described in the patent application (paragraphs 3-5 of the declaration). Declarant refers to publications "plant Biotechnology Journal (2003) and Applied Microbiology and Biotechnology (2003). Paragraph 6 of the declaration states that the expression of laccase in plant parts other than to the plant seed, and other than to the cell wall resulted in either low expression levels or the plant died. Declarant states that plants other than maize are expected to be useful for the production of laccase, since

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transformation of monocot and dicot plants are well established long before the filing date of this application (paragraph 7 of the declaration).

The Declaration has been fully considered but was found persuasive only with regard to the enablement of the production of laccase at levels of at least about 10% total soluble protein, wherein laccase is targeted to the cell wall of the seed of a transgenic plant. However, none of the rejected claims recite that the expression of laccase is targeted to the seed, and to the cell wall (or recite a construct comprising seed-specific promoter and signal sequence that targets expression of laccase to the cell wall). The Declaration does not address the rejection to claims that recite any laccase encoding sequence and laccase encoding sequences having 68% or 80% to 100% sequence identity to SEQ ID NO: 1 and nucleotide sequences that hybridize thereto under "highly stringency " conditions as recited in the claims.

Written Description

Claims 1-16 and 18-25 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 1/15/03. Applicant's arguments filed 06/13/03 have been considered but are not deemed persuasive.

Applicant argues that the claims are drawn to transformation of plants with a laccase encoding gene and its high level of expression of laccase in plants, rather than

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any laccase encoding gene. Applicant's argument implies that description of nucleotide sequences employed in the invention is not required, since any of the known laccase genes can be employed. Applicant asserts that the written description requirement of the claimed invention is satisfied because the working examples and procedures described in the specification that resulted in high expression levels of laccase in transgenic plants are sufficient to provide written description of the claimed invention (last full paragraph of page 9 of the response).

These arguments are not persuasive. Taking the last assertion first, it should be noted that the requirement of written description is separate and distinct from the enablement requirement. To satisfy the former, "a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention". The experimental procedures described in the specification that resulted in high expression level of laccase in the plant are enablement issues rather than written description.

The claimed invention is drawn to a transgenic plant, plant cell and seed comprising any nucleotide sequence encoding laccase, and a method of transforming plants with said laccase encoding nucleotide sequence for the production of specific levels of laccase. In contrast, the instant specification describes transgenic plant comprising a laccase nucleotide sequence from a single fungal species and a method that employs said single fungal nucleotide sequence. These are genes claims. To satisfy written description of species-genus claims, a representative species of laccase encoding nucleotide sequences must be described in the specification or known in the

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prior art. In the instant case, there is no indication that other than fungal and plant laccase encoding nucleotide sequences are known in the prior art. Since the laccase encoding nucleotide sequences of the invention are not adequately described, plants, plant cell, seed, and vectors and methods that employ said nucleotide sequences are similarly not described. In addition, substantial variation in structures and function are expected among nucleotide sequences that hybridize to SEQ ID NO: 1 under any stringency conditions because various "highly stringency" conditions would yield sequences unrelated to SEQ ID NO: 1. Therefore, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that one skilled in the art would recognize that Applicants are in possession of the invention as broadly claimed, as stated in the last Office action. Therefore, the rejection is maintained.

Remarks

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

9/5/03

Mai



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